K083561

Section 6: 510(k) Summary

FEB 11 2009

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M Squared Associates, Inc.
901 King Street, Suite 200
Alexandria, Virginia 22314
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Facsimile: 703-562-9797
Establishment Registration Number: 3005846524

Manufacturing:

Implants

Elos AB
Bäckedalsvägen 6
SE-540 16Timmersdala, Sweden.
Registration Number: 3003847101

Pinol AS
Engsvej 33
DK-3330 Gorlose, Denmark.
Registration Number: Not yet available

Packaging Facility

Wesley Coe Ltd
Gas Lane
Ely, Cambridgeshire
CB7 4GH, UK
Registration Number: 8044131

Sterilization Facility

Swann-Morton Ltd
Owlerton Green
Hillsborough,
Sheffield, S6 2BJ, UK
Registration Number: 9611194

K083561

Date submitted: November 25, 2008

Proprietary Name: Neoss ProActive Implant

Common Name: Dental implant

Classification Status: Class II

Product Codes: DZE

Regulation: 872.3640 Implant, Endosseous, Root Form

Predicate Device: Neoss Bimodal Implant K043195

Device Description:

The Neoss ProActive is an modified version of the Neoss Bimodal Implant (K043195). Identical to K043195, the ProActive Implant is a threaded, internal abutment connection, root-form titanium dental implant. The ProActive assortment consists of a number of implants with a diameter of Ø3,5 to Ø5,5 mm and lengths between 7,0 – 19.0 mm having the same internal abutment dimension independent of implant diameter. The internal connection being equipped with interlocking elements for an insertion tool and the non-rotational locking of the abutment. Supplied sterile.

Indication for Use: as per K043195, as cleared for Neoss Bimodal Implant

The Neoss ProActive Implant is for single-stage and two-stage surgical procedures and cement or screw retained restorations.

The Neoss ProActive Implant are intended for immediate placement and function on single tooth and /or multiple tooth applications recognizing sufficient bone stability and appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be splinted with a bar.

Summary of Technological Characteristics:

The modification to the Neoss Bimodal Implant since its previous clearance in K043195 is a change to the surface finish process only. The modifications are changes required to improve device performance. In animal testing, grit-blasted and acid-etched surfaces exhibit an increase in the strength of osseointegration when compared to machined surfaces. Additionally, in animal testing, grit-blasted and acid-etched surfaces exhibit an increased

bone to implant contact when compared to grit-blasted surfaces. These minor differences do not affect the safety or performance of the device and do not change the intended use of the ProActive Implant when compared to the Neoss Bimodal Implant.

Summary of Nonclinical Testing:

Based on the Risk Analysis, performance testing was conducted to confirm compliance to device specifications; all functions were verified to operate as designed.

Substantial Equivalence Discussion:

The change to the surface finish process of the Neoss ProActive Implant does not change the intended use nor do they affect the safety and effectiveness as compared to the Neoss Bimodal Implant previously cleared in K043195.

Conclusion:

The modified Neoss ProActive Implant has the following similarities to the Neoss Bimodal Implant previously cleared in K043195:

- has the same indicated use,
- uses the same operating principle,
- incorporates the same basic device design and physical properties,
- incorporates the same materials.

Therefore the modification to the Neoss ProActive Implant can be found substantially equivalent to the Neoss Bimodal Implant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Neoss Limited
C/o Ms. Cherita James
M Squared Associates, Incorporated
901 King Street, Suite 200
Alexandria, Virginia 22314

FEB 11 2009

Re: K083561
Trade/Device Name: Neoss ProActive Implant
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: January 9, 2009
Received: January 12, 2009

Dear Ms. James:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 5: Indications for Use Statement

510(k) Number (if known): K083561

Device Name: Neoss ProActive Implant

Indications For Use: The Neoss ProActive Implant is for single-stage and two-stage surgical procedures and cement or screw retained restorations.

The Neoss ProActive Implant is intended for immediate placement and function on single tooth and /or multiple tooth applications recognizing sufficient bone stability and appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be splinted with a bar.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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